K081186

Section I
510(k) Summary

MAY 23 2008

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1. **Applicant's Name and Address**

Straumann US (on behalf of Institut Straumann AG)
60 Minuteman Rd.
Andover, MA 01810
Telephone Number: 800-448-8168, ext 2513
Fax Number: 978-747-0023
Contact Person: Elaine Alan
Regulatory Affairs Specialist
Date of Submission: April 25, 2008

2. **Name of the Device**

Trade Name:	RN Healing Cap, Concave
Common Name:	Abutment, Dental, Endosseous implants
Classification Name:	Abutment, Dental, Endosseous implants
Regulation Number:	§872.3630

3. **Legally Marketed Device to which Equivalence is Claimed (Predicate Device)**

RN Esthetic Healing Caps, K960634

4. **Description of the Device**

The Straumann Dental Implant System is an integrated system of endosseous dental implants, which are designed to support prosthetic devices for partially or fully edentulous patients. The system consists of a variety of dental implants, permanent and temporary abutments, healing caps and surgical and prosthetic parts and instruments. The device covered in this submission is a healing cap.

5. **Intended Use of the Device**

Healing caps are intended to be placed into dental implants to protect the inner configuration and shoulder of the implant and to maintain, stabilize and form the soft tissue during the healing phase.

6. **Technological Characteristics**

The proposed healing cap is substantially equivalent to the currently cleared device. The intended use, material, basic design and fundamental operating principles are identical to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 23 2008

Institut Straumann AG
C/O Ms. Elaine Alan
Regulatory Affairs Specialist
Straumann USA
60 Minuteman Road
Andover, Massachusetts 01810

Re: K081186
Trade/Device Name: RN Healing Cap, Concave
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: II
Product Code: NHA
Dated: April 25, 2008
Received: April 28, 2008

Dear Ms. Alan:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

K081186

Device Name: RN Healing Cap, Concave

Indications for Use:

Healing Caps are intended for placement onto dental implants to protect the inner configuration and shoulder of the implant and to maintain, stabilize and form the soft tissue during the healing phase.

Prescription Use ____X____ AND/OR Over-The-Counter Use_____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

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